

510(k) SUMMARY

MAR 16 2012

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CONTACT NAME: Paul Swift, Regulatory Affairs Specialist
DATE PREPARED: March 7, 2012

DEVICE TRADE NAME: BD BACTEC Plus Aerobic/F (plastic)

DEVICE COMMON NAME: Aerobic blood culture medium

DEVICE CLASSIFICATION: 21 CFR§866.2560, Class I

PREDICATE DEVICE: BD BACTEC PLUS Aerobic/F medium (K921133)

INTENDED USE:

The BD BACTEC Plus Aerobic/F medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC fluorescent series instruments.

DEVICE DESCRIPTION:

The sample to be tested is inoculated into one or more vials which are inserted into the BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO₂ produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO₂ present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

Resins have been described for the treatment of blood specimens both prior to and after their inoculation into culture media. Resins have been incorporated into BACTEC culture media to enhance recovery of organisms without a need for special processing.^{1,2,3,4}

¹ Wallis, C. et al. 1980. Rapid isolation of bacteria from septicemic patients by use of an antimicrobial agent removal device. J. Clin. Microbiol. 11:462-464.

² Applebaum, P.C. et al. 1983. Enhanced detection of bacteremia with a new BACTEC resin blood culture medium. J. Clin. Microbiol. 17:48-51.

³ Pohlman, J.K. et al. 1995. Controlled clinical comparison of Isolator and BACTEC 9240 Aerobic/F resin bottle for detection of bloodstream infections. J. Clin. Microbiol. 33:2525-2529.

⁴ Flayhart, D. et al. 2007. Comparison of BACTEC Plus blood culture media to BacT/Alert FA blood culture media for detection of bacterial pathogens in samples containing therapeutic levels of antibiotics. J. Clin. Microbiol. 45:816-821.

DEVICE COMPARISON:

The BD BACTEC Plus Aerobic/F (plastic) differs from the BD BACTEC Plus Aerobic/F (K921133) in the following ways:

- The medium in the new device is contained in a plastic bottle; whereas, the medium in the predicate device is contained in a glass bottle.
- The new device's sensor has been adjusted to obtain equivalent performance to that of the predicate device.
- The sugar concentration of the growth medium in the new device has been increased by 0.2%.
- The new device weighs approximately 60% less than predicate device.
- The new device measures 5.0 inches high compared to the predicate device height of 5.6 inches.

The BD BACTEC Plus Aerobic/F (plastic) is similar to the BD BACTEC Plus Aerobic/F (K921133) in the following ways:

- Both the new and predicate devices are used for the qualitative aerobic culture and recovery of microorganisms from human blood.
- Both devices are intended to be used with the BD BACTEC fluorescent-series of blood culture instruments.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same incubation and agitation parameters to both devices.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same growth and detection algorithms to both devices.
- Both devices are incubated at 35° C ($\pm 1.5^\circ$ C) for a period of up to 120 hours.
- Both devices incorporate resins for the adsorption of antimicrobials that may be present in clinical samples.
- Both devices incorporate a sensor that detects increases in CO₂ within the bottle as a result of organism growth. Both devices require a sample volume of 3 – 10 mL of blood.

- Both devices utilize 30 mL of enriched soybean casein digest broth as the growth medium.
- Both devices have a maximum blood to broth ratio of 1:4.

SUMMARY OF PERFORMANCE DATA

Analytical Studies:

Instrument Time to Detection

A total of 726 paired sets were positive in both the new and predicate devices. There was no significant difference in recovery between the BD BACTEC Plus Aerobic/F blood culture medium contained in plastic bottles and the predicate device contained in glass bottles. The Wilcoxon estimated median TTD difference for the 726 positive sets is 0.083 hours (5 minutes).

The following organisms exhibited TTD differences of greater than 1 hour (plastic vials minus glass vials): *Candida glabrata* (-2.83), *Cryptococcus neoformans* (-1.67), *Haemophilus parainfluenzae* biotype I (1.33), *Micrococcus luteus* (2.83), *Leuconostoc* spp. (8.00) (i.e., *Candida glabrata* and *Cryptococcus neoformans* recovered faster in the new device; whereas *Haemophilus parainfluenzae* biotype I, *Micrococcus luteus* and *Leuconostoc* spp. recovered faster in the predicate device). *Micrococcus luteus* is rarely implicated as a cause of human infections and is usually considered a contaminant of clinical specimens. *Leuconostoc* spp. is very rarely isolated in blood culture specimens and when it is, it is often not clinically significant.

The data indicate that the effect of differences between the new and predicate devices on TTD under these test conditions was minimal and that the new device performs equivalently to the predicate device.

Percent Recovery

A total of 738 paired sets were evaluated in the Percent Recovery comparison. Of those, 726 paired sets were positive in both the new and predicate devices (98.4%). The McNemar p-value for this data set equals 1. The data indicate that the effect of differences between the new and predicate devices on percent recovery under these test conditions was not statistically detectable and that the new device performs equivalently to the predicate device.

Leuconostoc spp. was recovered in nearly all replicates of the new device (17 of 18) and the predicate device (16 of 18). This organism is rarely associated with human disease and is usually considered a probable contaminant.

False Positive Rate

A total of 240 paired sets were used to execute this study. The 240 paired sets were comprised of 80 bottles from each of 3 lots. The paired sets were inoculated with fresh human blood at varying levels as specified by the test protocol and entered into the BACTEC blood culture instrument. It was expected that each bottle would be instrument-negative following the complete protocol (120 hours). There were no false positive bottles of the new device observed within the recommended usage range of blood

volumes (3 to 10 mL). Two false positive bottles were observed when inoculated with a blood volume outside of the recommended usage range for the device (<3 mL).

False Negative Rate

A total of 82 paired sets were evaluated for the determination of the False Negative Rate of the new device. There was one false negative result with the new device: *Leuconostoc* spp. with 3 mL of blood (plate count 35 CFU). The *Leuconostoc* species that failed to recover in the new device was a false negative based on the post-protocol subculture results. The *Leuconostoc* species is a slow-growing organism in both the new and predicate devices that typically detects late in protocol. *Leuconostoc* spp. was recovered in nearly all replicates of the new device (17 of 18). *Leuconostoc* is rarely isolated in blood culture specimens and, when it is, it is often not clinically significant.

BACTEC Instrument Compatibility

A total of 246 paired sets (new and predicate devices) were tested in each the BACTEC FX, BACTEC 9240 and BACTEC 9050 fluorescent-series blood culture instruments. A recovery comparison of the new device versus the predicate device results in a McNemar p-value of 1.00 across instruments, demonstrating that the performance of the new device is equivalent to the predicate device in each of the BACTEC fluorescent series blood culture instruments.

The BACTEC 9240 and BACTEC FX both did not have a statistically significant difference in time to detection between the new and predicate devices. The BACTEC 9050 exhibited a statistically significant difference in time to detection between the new and predicate devices. In the BACTEC 9050, the Wilcoxon median time to detection difference estimate is 0.417 hours (25 minutes) in favor of the predicate device.

Reproducibility

The new device was evaluated for reproducibility across lots in terms of time to detection and recovery. For each lot, there was no statistically significant difference observed in recovery comparing the new and predicate devices. Both Lots 1 and 3 exhibited no statistically significant difference in time to detection between the new and predicate devices. Lot 2 exhibited a statistically significant difference in time to recovery between the new and predicate devices due to the increased time to detection exhibited in the BACTEC 9050 instrument. The median time to detection difference exhibited by Lot 2 was 10 minutes.

Antimicrobial Neutralization Capability

Both the new and predicate devices incorporate resins to enhance the recovery of microorganisms by adsorption of antibiotics in the blood sample. A total of 18 drugs were tested with organisms that would be clinically treated with the antimicrobials. The battery of drugs selected was based on clinical importance and use and were intended to be representative of a wide variety of antimicrobial classes. The amount of antimicrobial added to each bottle represents the amount found in 7 mL of blood at or near the peak

serum level. Additionally, a supplemental study was conducted with representative class drugs tested at the level each selected organism for that particular drug is susceptible to.

A total of 377 drug-bug combinations per lot were tested. The results indicate that all three lots of the new device detected more drug-bug combinations than the predicate device. No statistically significant difference was observed in resin-dependent recovery with the new device compared to the predicate device. The following antimicrobials were included in this study:

• Amoxicillin/Clavulanate	• Aztreonam	• Ceftazidime
• Ciprofloxacin	• Ceftriaxone	• Cefotaxime
• Ertapenem	• Fluconazole	• Cefepime
• Gentamicin	• Imipenem	• Levofloxacin
• Meropenem	• Tetracycline	• Tigecycline
• Ticarcillin/Clavulanate	• Piperacillin/Tazobactam	• Vancomycin



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Becton Dickinson and Company
c/o Mr. Paul Swift
Regulatory Affairs Specialist/ Regulatory Affairs
7 Loveton Circle, Mail Code 614
Sparks, MD 21152

MAR 16 2012

Re: k113558

Trade/Device Name: BD BACTEC Plus Aerobic /F (plastic)
Regulation Number: 21 CFR§866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I
Product Code: MDB
Dated: March 9, 2012
Received: March 15, 2012

Dear Mr. Swift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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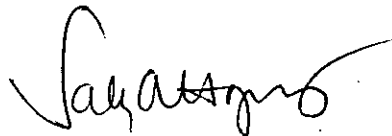
of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices Radiological Health

Enclosure

Indication for Use510(k) Number (if known): K113558Device Name: BD BACTEC Plus Aerobic/F (plastic)**Indication For Use:**

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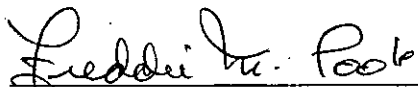
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety510(k) K113558